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NHS England's revised Individual Funding Request policy: unfair, unacceptable, and probably unlawful

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INTRODUCTION

The Individual Funding Request (IFR) process requires consideration of funding for individual cases on an exceptional basis when a treatment is not normally available on the NHS. IFRs may involve a treatment for which there is no commissioning policy, or where there is a commissioning policy that states that the treatment is not normally funded. NHS England (NHSE) is responsible for commissioning specialised services in England and for considering IFRs that relate to those services, including, for example, cancer drug treatments.

NHS England conducted a public consultation on its IFR policy which closed in January 2017. Ten months elapsed until the outcome was published in November 2017 (NHS England 2017a), an extended period of time explained as being required to 'refine' the policy (NHS England 2017b). Clinicians and managers within the NHS, as well as patients and patient groups, had many concerns about the previous policy, as evidenced in the response to the consultation (NHS England 2017b). Unfortunately, the new policy retains many of the flaws of its predecessor. The policy does not allow for full consideration of requests and may therefore prevent patients from accessing treatment that should be made available. This is not only unfair, it is ethically unacceptable, and may well be unlawful.

In this paper we will focus on two aspects of the policy that prevent cases from being properly considered: the screening process and the rejection of cases that are deemed to be part of a 'cohort'.

THE SCREENING PROCESS

Before a case can be considered by the IFR Panel it must pass a process which screens for sufficient information, service developments and clinical exceptionality. Screening for sufficient information checks that NHSE is the responsible commissioning body, that the treatment is not already approved - which would make the IFR unnecessary – and that the paperwork is complete. Screening for service developments is covered later in this paper under 'Cohorts'. It is screening for clinical exceptionality which is the focus here.

The screening group considers each case and if it "considers that there is not an arguable case for clinical exceptionality, the IFR will not proceed further through the process and will be declined" (NHS England 2017a). In effect, therefore, the group is given authority to prejudge the decision of the IFR Panel and reject a case. The generally-accepted approach to IFRs within the NHS is that screening should exclude only those cases "for which there clearly is no clinical case" (NHS Confederation 2008), an approach which the phrase 'arguable case' may be intended to capture. However, in practice, the previous process did not only reject implausible cases, it also rejected cases with strong prima facie claims to exceptionality, and nothing in the new policy alters this. Taking a real case example considered under the previous policy:

- Unusually young, ovarian cancer patient with an unusual presentation and initial diagnostic uncertainty.

- Low grade but aggressive tumour; standard treatment would be surgery, but the tumour was inoperable.
- Chemotherapy regimen recommended by national centre.
- 1 chemotherapy agent stopped after severe (exceptional) allergic reaction; multiple admissions for toxicity and minimal response to chemotherapy.
- After 4 cycles disease showed only minimal response and remained inoperable. Patient referred to national centre which advised to continue to 6 cycles then anti-angiogenic therapy to be continued ongoing.
- Unusually positive sustained and on-going response to treatment: patient completely asymptomatic with no side effects. Exceptional compared to the usual very poor response of low grade ovarian cancer.
- IFR request to extend treatment beyond standard number of cycles as stopping treatment would be likely to lead to rapid progression; and evidence suggests that 2nd line chemotherapy would be extremely unlikely to be effective given the low grade nature of the cancer; also unlikely to be tolerated, given previous poor tolerance of chemotherapy.

The rejection letter from NHSE said, “As an arguable case has not been made to forward this request to the IFR Panel, it will not be taken further under the IFR Process. There are no grounds for appealing this decision.” While we cannot say with certainty that this case would have been approved by the IFR Panel, it should not have been dismissed as unarguable and therefore unworthy of consideration.

In the policy it is noted that “the IFR Panel and its processes should reflect best practice as outlined in the National Prescribing Centre Handbook of Good Practice Guidance” (NHSE England 2017a). This Handbook (Department of Health 2009) carries the authority of the Department of Health, and includes a set of Guiding Principles on processes for IFR decision making. It would seem probable that the statement in the NHSE policy gives patients a legally-enforceable legitimate expectation that the processes set out in the Handbook will be followed. An example of the application of this legal principle in the NHS is found in Royal Brompton & Harefield NHS Foundation Trust v Joint Committee of Primary Care Trusts, Croydon Primary Care Trust (2011).

The IFR Panel consists of ten people with a range of competencies, plus more for particularly complex cases, and therefore does meet the best practice recommendations that “defined membership should include a balanced mix of clinically and managerially-focused professionals and lay persons” (Department of Health 2009). By contrast, the screening group consists of only three people, with only two voting members, and does not have the range of competencies that the Department of Health and NHSE deem necessary for an IFR Panel; but it is nevertheless able to decline cases. Elsewhere in the policy NHSE states “It would be impossible to convene a properly constituted panel in a very short timescale. Decisions taken by one or two panel members acting alone increases risks of coming to the wrong decision”. By NHSE’s own admission, the screening group is not equivalent to a ‘properly constituted panel’ and therefore should not be making *de facto* IFR decisions. This internal inconsistency may very well conflict with principles of administrative law which “requires that the decisions of NHS bodies and local authorities are rational, procedurally fair and within their powers” (Department of Health 2015).

Furthermore, a decision of the screening group is unchallengeable within the policy: “The IFR policy does not provide a right for the case to be considered by the IFR Panel and does not provide a right to request that the screening outcome should be reviewed by the IFR Process Review Panel.” Hence, a review of an IFR is permitted by NHSE when it is declined by the (properly-constituted) IFR Panel, but – save for when new clinical evidence is introduced – not when it is declined by the (improperly-constituted) screening group. The exclusion of screening group decisions from the review/appeals process is troubling. It appears to conflict with the Guiding Principles (Department of Health 2009) which recommend “an appeals process for decisions made on IFRs” (importantly, not ‘decisions made by an IFR Panel’, but ‘decisions made on IFRs’). This not only frustrates a legally-enforceable legitimate expectation established by the Guiding Principles, but is unacceptably cruel from an ethical standpoint, as it means that the unfairly-declined patient will have to seek remedy instead via legal action or other mechanisms of administrative redress. A proportion of IFR patients will be requesting a ‘last chance’ treatment and should not have to spend their final months either accepting a refusal to even consider their case, or going through the stress of legal action or other forms of challenge. Instead, many such patients will simply give up.

Given its internal inconsistency and conflict with the Guiding Principles that it purports to follow, there are good grounds for thinking that the NHSE screening process may be regarded as unlawful if challenged in court. NHSE should not put itself in the position where it takes this risk; and should not put patients in the position where they are driven to test the lawfulness of its processes.

COHORTS

Another aspect of the process also raises significant concerns: the management of cases that are considered to be part of a ‘cohort’.

The IFR process will only proceed if “the patient’s clinical presentation is so unusual that they could not be considered to be part of a defined group of patients in the same or similar clinical circumstances” and this judgement may be made by the screening group or the IFR Panel. Rather than taking a decision for that individual patient, NHSE’s approach is that a policy should be developed to cover all such patients in the cohort. This is not inappropriate in principle, but it is unsatisfactorily implemented.

The patient with exceptionally severe disease, an exceptional combination of conditions, or an exceptional adverse response to standard treatment, will not be considered if there could be a small number of other patients in similar circumstances. The previous version of the IFR Policy defined a cohort as 5 per year in one of the four NHSE regions, the largest with a population of 15 million (NHS Commissioning Board 2013). This threshold is extremely low – it must be possible for 5 people in 15 million all to be exceptional. A threshold of 5 in 15 million or even lower is close to saying that only a unique patient is not part of a cohort and can be considered by the IFR Panel. Since a court in a previous challenge to an IFR had noted that “it must be borne in mind that exceptional is not the same as unique and that there should not be an approach that denies that any but an extreme case is regarded as exceptional” (*S (a child) v NHS England* (2016)), the lawfulness of this approach would seem to be highly questionable.

The revised policy has retained the cohort principle, but has removed the threshold altogether on the basis that “operational practice” was that “clinical policy development would likely be triggered before the defined number was reached” (NHS England 2017b). Therefore, when patients are deemed to be part of a cohort, one might assume that a policy for that treatment would necessarily and rapidly be produced: there would be very few IFRs to be considered and a huge flow of policies to cover small groups of patients with unusual clinical circumstances. The response to the consultation notes that “concern was expressed about the robustness of the process for IFR “cohorts” triggering commissioning policies and the length of time that process can take” (NHS England 2017b). Despite this, there is no process to ensure that the rejection of a ‘cohort’ IFR will lead to development of a policy. NHSE takes no responsibility to initiate policy development, instead the clinician requesting the IFR “will then be redirected to the relevant contact point to start the process” (NHS England 2017a). If that clinician does not start the process, nothing will happen. The IFR Standard Operating Procedures suggest that the IFR team will produce a regular report to inform the annual policy development programme, (NHS England 2017c). However, when contacted in November 2017 and again in February 2018, NHSE had no process in place to create such a report.

The policy development process has a number of stages that can stop the policy progressing and there are limits on the number of policies which may be approved in any year. There is no guarantee that any particular cohort-related policy will be developed this year, next year or ever. Policy development is sometimes unsatisfactorily slow for treatments that apply to a whole affected population, therefore it is unlikely that there will be timely development of policies for an unusual sub-group of patients with less clear evidence. Patients who are refused IFR consideration because they are part of a cohort may wait indefinitely, even for an interim policy to be developed. Refusing to consider an IFR because a policy is required and then failing to produce a policy leaves patients in limbo, an example being the widely reported case of Everolimus for Tuberous Sclerosis patients (Tuberous Sclerosis Association 2016).

It is well understood within the NHS that administrative law prevents blanket bans on access to treatment (R v North West Lancashire Health Authority, ex parte A, D and G (1999)). There will be a length of time beyond which refusing to consider IFRs while waiting for a policy effectively becomes a blanket ban on treatment for those patients, which would be unlawful. The ethical acceptability of this position is also highly questionable, given that NHS England is aware that it has no process in place to ensure that a suitable policy will ever be developed.

CONCLUSION

The NHSE IFR policy places unfair, unacceptable and probably unlawful barriers in the way of doctors and patients who have a right to have their cases properly considered. Even if those barriers are overcome, there are significant flaws in how the NHSE IFR Panel makes decisions on ‘clinical exceptionality’, but these are beyond the scope of this paper. To have even a chance of a fair decision, patients must be in a position to have their cases heard by the Panel.

Responses to its consultation (including those submitted by one of the present authors) should have ensured that NHSE was aware of the shortcomings with its existing IFR policy, yet it has chosen to continue with it. NHSE should restrict the screening process to its proper function. It should also

establish a process for policy development in reasonable timescales for all cohort IFRs and, if this cannot be done, it will have to accept that such cases will have to be considered as IFRs until corresponding policies are developed. It cannot be legitimate for the policy to remain as it currently stands while hundreds more patients face having their cases inappropriately dismissed.

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